

3.0 510(k) SUMMARY

3.1 Submitted by: Church & Dwight Co., Inc
469 North Harrison Street
Princeton, NJ 08543

K070054

3.2 Contact Person: Cynthia Davidson
Manager, Regulatory Affairs
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MAY - 4 2007

3.3 Date Prepared: December 28, 2006

3.4 Proprietary Name: FIRST RESPONSE® GOLD™ Digital Pregnancy Test

3.5 Common Name: At-home Pregnancy Test (OTC)

3.6 Classification Name: Human chorionic gonadotropin (hCG) test system
[21 CFR §862.1155] 75 LCX; Class II

3.7 Predicate Device: CLEAR BLUE® Easy Digital Pregnancy Test (Unipath
Ltd., UK), K041404

3.8 Description of Device: The FIRST RESPONSE® GOLD™ Digital Pregnancy Test is a human chorionic gonadotropin (hCG) test system. It is a device intended for use by the lay user in the early detection of pregnancy by the detection of hCG, a placental hormone in urine. The device detects the presence of hCG in the urine of a pregnant woman by way of a series of immunochemical reactions on a chromatographic strip contained within a plastic housing, which is integral with the digital component that reads and displays the result of the immunochemical reactions on the Display Screen of the device in a manner similar to the predicate device.

3.9 Intended Use and Indication for Use of the Device: The FIRST RESPONSE® GOLD™ Digital Pregnancy Test is an *in vitro* diagnostic test device intended for use by the lay user for the early detection of pregnancy prior to the expected menses. The test is indicated for use from four days before the expected period, that is, five days before the missed period.

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3.10 Technological Characteristics: The subject 510(k) device and its analog counterpart First Response Early Result Pregnancy Test (K#030258) utilize the identical immunochemical principles for the assay of hCG: an immunochromatographic assay using colloidal gold as a direct label. The subject 510(k) device differs in that it provides a digital display of the test result for the consumer to read in place of the colored lines of the above referenced analog device. The digital version of the device incorporates into the stick housing electronic and optical components along with a microprocessor and specific algorithms capable of determining and correctly interpreting the reaction result and displaying a simple "YES+" or "-NO" on a Display Screen. The digital device is battery powered and will display the result for at least thirty minutes after completion of the reaction. All components are integrated and unitized into the stick housing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Church & Dwight Co., Inc.
c/o Ms. Cynthia Davidson
Regulatory Affairs Manager
469 North Harrison Street
Princeton, NJ 08543

MAY - 4 2007

Re: k070054

Trade/Device Name: FIRST RESPONSE® Gold™ Digital Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: April 11, 2007
Received: April 12, 2007

Dear Ms. Davidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K070054

Device Name: FIRST RESPONSE® GOLD™ Digital Pregnancy Test

Indications for Use: The First Response Gold Digital Pregnancy Test is an in vitro diagnostic test device intended for the early detection of pregnancy by the lay user up to five (5) days sooner than the day of the missed period (four (4) days before the day of the expected period). The test detects human chorionic gonadotropin in urine.

Prescription Use _____ AND/ OR Over-the Counter Use X
Part 21 CFR 801

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070054